

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: :  
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Birger Hjertman et al. :  
 :  
Serial No.: To be assigned : Art Unit: To be assigned  
 :  
Filed: Herewith : Examiner: To be assigned  
 :  
For: DELIVERY DEVICE AND : Atty Docket: 0151/00222  
METHOD FOR ITS :  
OPERATION :

PRELIMINARY AMENDMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to initial examination, please amend the above-captioned case as follows.

IN THE CLAIMS

Kindly cancel claims 1-39, 85 and 107 and amend claims 42, 45 and 46 as follows:

42. (Amended) The method of claim 40, characterized in that at least part of the container is translucent or transparent at the radiation frequency and that at least some radiation is transmitted into the container.

45. (Amended) The method of claim 44, characterized in that the initiation step comprises a reconstruction step.

46. (Amended) The method of claim 40, characterized in the step of moving the container in relation to the sensor system.

Kindly add new claims 108-110 as follows:

--108. (Added) The method of claim 41, characterized in that at least part of the container is translucent or transparent at the radiation frequency and that at least some radiation is transmitted into the container.

--109. (Added) The method of claim 43, characterized in that the initiation step comprises a reconstruction step.

--110. (Added) The method of claim 43, characterized in the step of moving the container in relation to the sensor system.--

### REMARKS

Claims 1-39 and 85 and 107 have been canceled and new claims 108-110 have been added.

The claims have been amended to eliminate multiple dependency and to improve their format. None of these amendments is believed to involve any new matter. Accordingly, it is respectfully requested that the foregoing amendments be entered, that the application as so amended receive an examination on the merits, and that the claims as now presented receive an early allowance.

Respectfully submitted,



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## APPENDIX

42. (Amended) The method of claim 40 [or 41], characterized in that at least part of the container is translucent or transparent at the radiation frequency and that at least some radiation is transmitted into the container.

44. (Amended) The method of claim 40 [or 43], characterized in that the initiation step comprises a reconstruction step.

46. (Amended) The method of claim 40 [or 43], characterized in the step of moving the container in relation to the sensor system.

39. The device of claim 38, characterized in a fixed arrangement of the support in relation to the mechanism or a housing.

40. A method for operating a preparation delivery device comprising a) a container for the preparation having, or being prepared for the arrangement of, an opening, b) a mechanism  
5 operable to deliver at least part of the preparation in the container through the opening, c) attachment means for connection of the container to the mechanism and d) a sensor system arranged to detect at least one predetermined property of the container or its content, characterized in the improvement comprising

transmitting radiation towards the container position or a part thereof to allow the radiation to be affected by the container position,

receiving at least a part of the affected radiation from at least an area part of the container position in a non-imaging way and

comparing the characteristics of the received radiation with a predetermined characteristic representative for the predetermined property to establish whether or not the predetermined property of the container is present.

41. The method of claim 40, characterized in that the radiation is affected by reflection, transmission, absorption and/or scattering.

42. The method of claim 40 or 41, characterized in that at least part of the container is translucent or transparent at the radiation frequency and that at least some radiation is transmitted into the container.

43. The method of claim 40, characterized in the step of moving the container in relation to stationary parts of the mechanism.

44. The method of claim 40 or 43, characterized in the step of performing an initiation step on the container.

45. The method of claim 44, characterized in that the initiation step comprises a reconstitution step.

46. The method of claim 40 or 43, characterized in the step of moving the container in relation to the sensor system.

47. The method of claim 46, characterized in that the speed of movement is less than 10 cm/sec.

48. The method of claim 40, characterized in that the speed is less than 1 cm/sec.

49. The method of claim 40, characterized in that container and sensor system are kept stationary in relation to each other during radiation reception.

50. The method of claim 40, characterized in that the radiation transmitted is in the non-visible range, preferably in the infrared range.

51. The method of claim 40, characterized in that the radiation received is de-focused.

52. The method of claim 40, characterized in that the radiation is transmitted in a divergent beam and the radiation is received from a divergent take up angle.

53. The method of claim 40, characterized in that that the radiation is transmitted and received in a broad space angle, preferably above 30 degrees.

54. The method of claim 40, characterized in transmitting and/or receiving a broadbanded radiation with a preferred frequency variation coefficient of at least plus and minus 1 percent of nominal frequency.

55. The method of claim 40, characterized in that transmitter and receiver are arranged facing in substantially the same direction an that at least some radiation received is reflected.

56. The method of claim 40, characterized in the step of maintaining transmitter and receiver at a distance from the container.

57. The method of claim 40, characterized in that the area covered by the receiver, expressed as the diameter of a circle with corresponding surface, is between 0.5 and 15 mm.

58. The method of claim 40, characterized in the step of providing a marking on the container readable by the sensor system.

59. The method of claim 58, characterized in providing the marking with more than two discrete levels.

60. The method of claim 58, characterized in providing more than one discrete marking areas.

61. The method of claim 60, characterized in reading the areas in sequence, statically or dynamically.

62. The method of claim 61, characterized in that the reading gives a step difference in the response.

63. The method of claim 58, characterized in providing a marking with differences in absorption or reflection.

64. The method of claim 40, characterized in positioning sensor and container to allow detection of a functional property of the container.

5 65. The method of claim 64, characterized in that the functional property is a container contour part, a plunger position, container content or a marking or modification designed to facilitate detection of a functional property.

66. The method of claim 64, characterized in also reading a marking on the container, statically or dynamically.

10 67. The method of claim 40, characterized in that in the comparing step the characteristic of the received radiation is a response representative for the total radiation received from said area covered.

68. The method of claim 67, characterized in that said establishment of property presence is based on a static response from the receiver.

15 69. The method of claim 67, characterized in that said establishment of property presence is based on a dynamic change from the receiver.

70. The method of claim 69, characterized in that the establishment involves recording a dynamic response versus time function from the receiver.

20 71. The method of claim 70, characterized in that more than one property presence is established.

72. The method of claim 71, characterized in that at least one marking property and one functional property is established.

73. The method of claim 40, characterized in that the transmitted radiation is modulated.

25 74. The method of claim 40, characterized in that the radiation is transmitted and received with stable orientation in relation to stationary parts of the mechanism.

75. The method of any of claims 40 to 74, characterized in that the container is a cartridge comprising a) a generally cylindrical barrel with a general symmetry axis and having a front end and a rear end, b) an opening or a preparation for an opening at its front  
30 end, c) at least one displaceable piston inserted in the barrel between the front end and the rear end.

76. The method of claim 75, characterized in that the cartridge is of dual or multi chamber type.

77. A method for operating a preparation delivery device comprising a) a container for the preparation having, or being prepared for the arrangement of, an opening, b) a mechanism  
5 operable to deliver at least part of the preparation in the container through the opening, c) attachment means for connection of the container to the mechanism and d) a sensor system arranged to detect at least one predetermined property of the container or its content, characterized in the improvement comprising

transmitting radiation towards the container position or a part thereof to allow the radiation to be affected by the container position,

receiving at least a part of the affected radiation and

comparing the characteristics of the received radiation with a predetermined characteristic representative for the predetermined property, being a functional property as defined. to establish whether or not the predetermined functional property of the container is present.

15 78. The method of claim 77, characterized in that the received radiation is used to reproduce details from the container position in at least two dimensions providing a representation in the form of pixels in the at least two dimensions.

79. The method of claim 78, characterized in refracting the received radiation to an image on a cathode ray tube or charge coupled device.

20 80. The method of claim 78, characterized in sweeping the container position point by point to produce an image.

81. The method of claim 77, characterized in transmitting and/or receiving a broadbanded radiation with a preferred frequency variation coefficient of at least plus and minus 1 percent of nominal frequency.

25 82. The method of claim 81, characterized in transmitting at least part of the radiation to the content of the container.

83. The method of claim 81, characterized in receiving at least part of the radiation as reflected in substantially the opposite direction as transmission.

84. The method of claim 77, characterized in that the functional property is a  
30 container contour or a plunger position.

85. The method of claim 77, characterized in any of the characteristics of claims 41 to 76.

86. A system of marked medical containers comprising a) at least two containers having different properties in at least one respect and b) at least one machine readable marking difference on each of said containers, the marking being designed to allow discrimination between said differences in properties, characterized in the improvement comprising

that the marking provides said difference by having at least one area with different absorbance or reflectance when irradiated with radiation in non-visible frequency ranges.

87. The system of claim 86, characterized in that the marking has more than two discrete levels.

10 88. The system of claim 86, characterized in that the marking has several discrete marking areas.

89. The system of claim 87, characterized in that the areas provide step level changes when read in sequence, statically or dynamically.

15 90. The system of claim 86, characterized in that the marking has differences in absorption or reflection.

91. The system of claim 86, characterized in that the markings provide an alteration in radiation frequency distribution.

92. The system of claim 86, characterized in that the marking has an opaque or reflecting backing.

20 93. The system of claim 86, characterized in that the areas have a size, expressed as the diameter of a circle with corresponding surface, of at least 1 mm, preferably at least 2 mm and most preferably at least 5 mm

94. The system of claim 86, characterized in that the containers have similar functional properties in at least one respect.

25 95. The system of claim 94, characterized in that the containers are similar in the respect that they are adapted to be used in the same medical delivery device.

96. The system of claim 94, characterized in that the containers are similar in that they contain at least one common medical compound.

30 97. The system of claim 86, characterized in that the difference in property comprises a difference in content medical compounds, content volume or content concentration.



98. A syringe cartridge type container, for use with a preparation delivery device, comprising a) a generally cylindrical barrel with a general symmetry axis and having a front end and a rear end, b) an opening or a preparation for an opening at its front end, c) at least one displaceable piston inserted in the barrel between the front end and the rear end and d) a machine readable marking on the container, characterized in the improvement comprising

that the marking includes at least one marking area with detectable absorbency or reflectance when irradiated with radiation in non-visible frequency ranges,

that the piston has at least one surface part with detectable absorbency or reflectance when irradiated with radiation in non-visible frequency ranges and that said piston surface part is exposed or exposable to the radiation through at least a part of the barrel and

that at least a part of said marking area and said piston surface part are located at the same position along the barrel symmetry axis.

99. The cartridge of claim 98, characterized in that at least a part along the barrel axis is free from marking allowing exposure of the piston.

100. The cartridge of claim 98, characterized in that in addition to the marking area covering the piston position at least one further marking area with different absorbency or reflectance is arranged along the barrel axis.

101. The cartridge of claim 98, characterized in that the cartridge is of dual or multi chamber type having more than one piston.

102. A machine readable marking system comprising at least two discrete areas of different detectable absorbencies when irradiated individually and providing a number of information carrying combination possibilities when read in predetermined sequence, characterized in the improvement comprising

that each area comprises more than two discrete levels of absorbencies.

103. The system of claim 102, characterized in that the marking has several discrete marking areas.

104. The device of claim 103, characterized in that moving means are present to read the areas in sequence, statically or dynamically.

105. The device of claim 102, characterized in that the marking has differences in absorption or reflection.

106. A device for analysis of an object comprising a) a radiation transmitter arranged to irradiate and be affected by the object and b) a receiver arranged to receive at least a part of the transmitted and affected radiation and to deliver a signal characteristic for the received radiation, characterized in the improvement comprising

5           that the transmitter is arranged to irradiate the object with non-imaging radiation,  
          that the receiver is arranged to collect non-imaging radiation affected by an area part  
of the object and

the receiver being designed to give an output response representative for the total radiation received from said area part.

107. The device of claim 106, characterized in any characteristic of claims 2 to 39.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
2	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
3	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
4	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
5	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81																			